510 (k) Summary

K080014

1. Submitter Information

Company name	TaiDoc Technology Corporation
Contact person	Yuhua Chen
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JUN - 9 2008

2. Name of Device

Trade Names	- Clever Chek TD-3250C Blood Glucose plus Blood pressure Monitoring System - Clever Chek TD-3250D Blood Glucose plus Blood pressure Monitoring System - Fora Comfort 2 in 1 Blood Glucose plus Blood Pressure Monitoring System
Common Names/Descriptions	- Blood Glucose and Blood Pressure Measurement System - Blood Glucose Test Strips
Classification Names	- Class II devices - 21 CFR Section 862.1345, Glucose Test System - 21 CFR Section 870.1130, Non-invasive Blood Pressure Measurement System

3. Predicate Device

Trade/Proprietary Name:	Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring System
Common/Usual Name:	- Blood Glucose and Blood Pressure Measurement System - Blood Glucose Test Strips
Manufacturer	TaiDoc Technology Corporation
510 (k) Number	K062800 NBW, CGA, DXN

4. Device Description

Clever Chek TD-3250C / Clever Chek TD-3250D / Fora Comfort 2 in 1 blood glucose plus blood pressure monitoring system consists of a monitor with arm cuff and test strips. The system utilizes an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions.

The system is able to provide blood pressure measurement which adopts the "oscillometric method" as the measuring principle. It provides the systolic pressure, diastolic blood pressure and pulse rate on an adult individual, over age 16, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the arm. The cuff circumference is limited to 9.4"~13.8" (24 ~35 cm) for arm.

5. Intended Use

Clever Chek TD-3250C / Clever Chek TD-3250D / Fora Comfort 2 in 1 blood glucose plus blood pressure monitoring system is indicated for the quantitative measurement of glucose in fresh capillary whole blood taken from the finger and the alternative sites for self testing by persons with diabetes in the home or by healthcare professionals in healthcare facilities. Testing is done outside the body (in vitro diagnostic use).

The alternative site testing (the palm, the forearm, the upper arm, the calf and the thigh) in this system can be used only during steady-state blood glucose conditions.

The system is also intended to be used to non-invasively measure the systolic and diastolic blood pressure and pulse rate of an adult individual, over age 16, at home. The blood pressure is measured by using a technique in which an inflatable cuff is wrapped around the arm. The cuff circumference is limited to 9.4" ~ 13.8".

Above systems offer wireless communication function which is able to transfer the test result to other devices, such as PC.

6. Comparison to Predicate Device

Clever Chek TD-3250C / Clever Chek TD-3250D / Fora Comfort 2 in 1 blood glucose plus blood pressure monitoring system has equivalent technological characteristics and intended use as the Clever Chek TD-3250 blood glucose plus blood pressure monitoring system (K062800).

7. Performance Studies

The performance of Clever Chek TD-3250C / Clever Chek TD-3250D / Fora Comfort 2 in 1 blood glucose plus blood pressure monitoring system was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that the above blood glucose plus blood pressure monitoring system is suitable for its intended use.

8. Conclusion

Clever Chek TD-3250C / Clever Chek TD-3250D / Fora Comfort 2 in 1 blood glucose plus blood pressure monitoring system demonstrate satisfactory performance and are suitable for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Taidoc Technology Corporation
c/o Yuhua Chen
6F, No. 127, Wugong 2nd Rd.
Taipei County, 241
Taiwan (ROC)

JUN - 9 2008

Re: k080014
Trade/Device Name: Clever Chek TD-3250C Blood Glucose plus Blood Pressure Monitoring System
Clever Chek TD-3250D Blood Glucose plus Blood Pressure Monitoring System
Fora Comfort 2 in 1 TD-3260 Blood Glucose plus Blood Pressure Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Monitoring System
Regulatory Class: Class II
Product Codes: NBW, CGA, DXN
Dated: June 3, 2008
Received: June 4, 2008

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K080014

Device Name:
Clever Chek TD-3250C Blood Glucose plus Blood pressure Monitoring System
Clever Chek TD-3250D Blood Glucose plus Blood pressure Monitoring System
Fora Comfort 2 in 1 Blood Glucose plus Blood Pressure Monitoring System

Indication For Use:

The Clever Chek TD-3250C Blood Glucose plus Blood pressure Monitoring System / Clever Chek TD-3250D Blood Glucose plus Blood pressure Monitoring System / Fora Comfort 2 in 1 Blood Glucose plus Blood Pressure Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus.

The alternative site testing in this system can be used only during steady-state blood glucose conditions.

The system is also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual, over age 16, at home.

The blood pressure is measured by using a technique in which an inflatable cuff is wrapped around the arm. The cuff circumference is limited to 9.4" - 13.8".

This system offers wireless communication function which is able to transmit the test result to other devices, such as PC.

Prescription Use _____ And/Or Over the Counter Use __X__.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K080014